Healthcare Audit and Enforcement Risk Analysis

Corporate Integrity Agreement (CIA) Summary - Life Sciences Report

April 2022 - July 2024 Updates

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To our Healthcare Management and Compliance Colleagues and Partners:

SunHawk Consulting produces this complimentary Report in an effort to promote the value of shared learnings, as well as to provide focused insights into healthcare related Corporate Integrity Agreements (CIA) settled over the last two years.

The United States Government may impose a Corporate Integrity Agreement (CIA) upon an entity when settling cases related to false claims submitted for services paid for by federally funded health care programs, The CIA establishes terms companies must meet including, in most cases, the engagement of an Independent Review Organization (IRO).

The Summary Reports included here provide focused insights into recently settled life science-related CIAs. The Summary Reports extract key data from published CIAs and US Department of Justice press releases to guide providers, payers, and life sciences companies in designing and refining their compliance programs. For your convenience and ease of use, the electronic version of this report includes hyperlinks to the original sources. The Report is updated regularly and new settlement matters are highlighted in orange to facilitate your review.

We appreciate feedback you believe would make this report more helpful to you or others. Should you wish to proactively audit or review your organizational activities as a result of these learnings, SunHawk's team of experts are happy to offer our assistance. Visit us at SunHawkConsulting.com and connect with us on LinkedIn for updates to this and other Healthcare Audit and Enforcement Risk Analyses.

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Life Sciences

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Cardiac Monitoring Companies to Pay More than $44.8 Million to Resolve False Claims Act Liability Relating to Services Performed by Offshore Technicians

Company Name: BioTelemetry, Inc. and CardioNet, LLC
Settlement: $44,875,000

Issue(s): False Claims Act, Cardiac Monitoring

The US DOJ announced that BioTelemetry Inc. and its subsidiary CardioNet LLC, both headquartered in Pennsylvania (collectively "BioTelemetry"), have agreed to pay $44,875,000 and enter into a five-year corporate integrity agreement to resolve allegations that they violated the False Claims Act by knowingly submitting claims to Medicare, TRICARE, the Veterans Health Administration, and the Federal Employee Health Benefits Program for heart monitoring tests that were performed, in part, outside the United States, and in many cases by technicians who were not qualified to perform such tests.

The United States alleged that CardioNet improperly billed Medicare and other federal health care programs for certain cardiac monitoring services — including Holter, event monitoring, and mobile cardiovascular telemetry (MCT) tests — that were performed overseas in violation of federal law that prohibits payment for services furnished outside the United States. More specifically, the government alleged that, in 2013, CardioNet contracted with a company located in India for the provision of diagnostic and analysis services of heart monitoring data. Although BioTelemetry set up a workflow that was designed to route electrocardiogram data, including data relating to cardiac events (ECG Data) for federal healthcare beneficiaries, to a domestic independent diagnostic testing facility for review and analysis, the government alleged that BioTelemetry — with the knowledge of then senior management — diverted certain federal beneficiaries' ECG Data to India when the domestic workflow became backlogged. BioTelemetry also allegedly sent ECG data for other federal beneficiaries directly to India for review. In 2014, over 29% of the ECG Data reviewed in connection with MCT tests, and over 78% of the ECG Data reviewed in connection with event monitoring tests, for Medicare patients were allegedly reviewed by technicians located in India. In 2015, those numbers allegedly rose to over 47% and over 88%, respectively. Although BioTelemetry began implementing technological controls in late 2015 to prevent personnel in India from accessing the domestic workflow, those controls were insufficient, and technicians in India allegedly continued to review and analyze some ECG Data for federal healthcare program beneficiaries thereafter.

The claims resolved by this settlement are allegations only, and there has been no determination of liability.

Date: 12/19/2022 **Entity Location:** Pennsylvania **Government Program(s):** Medicaid, TRICARE & Other Federal Programs

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Two Jacksonville Compounding Pharmacies and Their Owner Agree to Pay at Least $7.4 Million to Resolve False Claims Act Allegations

Company Name: Smart Pharmacy, Inc., SP2, LLC
Settlement: $7,400,000

Issue(s): False Claims Act, Improper Waiving of Patient Copays

The Justice Department announced that Smart Pharmacy, Inc., SP2, LLC, and owner Gregory Balotin have agreed to pay at least $7.4 million and enter into a three-year corporate integrity agreement to resolve lawsuits filed in Jacksonville, Florida, alleging they violated the False Claims Act by adding the antipsychotic drug aripiprazole to topical compounded pain creams to boost reimbursement and by routinely waiving patient copayment obligations.

Aripiprazole, which is sold under the brand names Abilify, Abilify Maintena, and Aristada, is approved by the U.S. Food and Drug Administration to treat a number of psychological conditions such as schizophrenia and Tourette's disorder. The United States alleged that the defendants crushed aripiprazole pills approved for oral use and included them in compounded creams used topically for pain treatment, while knowing that there was not an adequate clinical basis to do so. The defendants allegedly included the drug in the pain creams to increase their profits on prescriptions paid for by Medicare Part D and TRICARE, the federal health care program for active duty military personnel, retirees, and their families. Both Medicare Part D and TRICARE reimburse pharmacies for the individual ingredients included in compounded drugs, thus defendants increased their reimbursement by adding aripiprazole to the combination of drugs used in their pain creams.

The government also alleged that the defendants improperly waived patient copayments to induce patients to accept the pain cream prescriptions. Although copayments may be waived in certain unique circumstances, such as on the basis of an individualized assessment of a patient's financial hardship, the defendants allegedly routinely waived copayments without regard to patient need.

The claims resolved by this settlement are allegations only, and there has been no determination of liability.

Date: 06/15/2022 **Entity Location:** Florida **Government Program(s):** Medicare, TRICARE

BioReference Laboratories and Parent Company Agree to Pay $9.85 Million to Resolve False Claims Act Allegations of Illegal Payments to Referring Physicians

Company Name: Opko Health, Inc. and Bioreference Health, LLC.
Settlement: $9,850,000

Issue(s): False Claims Act, Stark Law, Anti-Kickback

The U.S. DOJ announced that BioReference Health LLC, formerly known as BioReference Laboratories, Inc., (BioReference), and OPKO Health, Inc. (OPKO) have agreed to pay $9.85 million enter into a five-year corporate integrity agreement to resolve alleged violations of the False Claims Act arising from BioReference's payment of above-market rents to physician landlords for office space in order to induce referrals from those physicians to BioReference.

BioReference, a subsidiary of OPKO, is headquartered in New Jersey and is one of the largest clinical laboratories in the United States.

BioReference and OPKO have agreed to pay $9.85 million to resolve allegations that, between January 2013 and March 2021, BioReference made lease payments to physicians and physician groups for the rental of office space for amounts that exceeded fair market value, in violation of the Physician Self-Referral Law and the Anti-Kickback Statute.

As part of the settlement, BioReference admitted that it rented the office space from the specified physician practices for Patient Service Centers (PSCs), where patients could have their blood samples taken. In calculating payments under certain PSC lease arrangements, BioReference inaccurately measured the amount of space BioReference would use exclusively and included a disproportionate share of common spaces. BioReference analyzed referrals from nearby health care providers — including physician-lessors — when deciding whether to open, maintain or close PSCs. Following OPKO's acquisition of BioReference, the companies conducted multiple internal audits that showed that the payments to the specified physician-lessors exceeded fair market value. BioReference did not report or return any overpayments to federal health care programs.

The claims resolved by this settlement are allegations only, and there has been no determination of liability.

Date: 07/14/2022 **Entity Location:** New Jersey **Government Program(s):** Other Federal Programs